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**2023/0126 (COD)**  
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**WK 16641/2025 INIT**

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**NOTE**

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From: Presidency  
To: Delegations

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N° prev. doc.: 16177/25; 16178/25; 16248/2025  
N° Cion doc.: 8851/23, 8869/23, 8887/23, 8894/23

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Subject: Supplementary Protection Certificate (SPCs)  
- Rotation mechanism for the designation of the rapporteur and co-rapporteurs

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With a view to facilitating the discussions at the meeting of the Working Party on Intellectual Property on 5 December 2025, delegations will find attached a note which further elaborates on the functioning of the rotation mechanism for the designation of the rapporteur and co-rapporteurs.

This policy paper is to be read in conjunction with the Presidency revised texts on the proposal for a Regulation on the SPCs for medicinal products (recast) set out in doc. 16177 /25 and on the proposal for a Regulation on unitary SPCs for medicinal products as set out in doc. 16178/25. Additionally, it should be read in conjunction with the stock taking paper s et out in doc. 16248/25.

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WK 16641/2025 INIT

**LIMITE**

**EN**

## SPC reform

### Draft rotation mechanism for the designation of (co-)rapporteurs

#### A. Basic principles

For any unitary or combined or centralised SPC application, the rapporteur and the two co-rapporteurs will be selected among the related network members, i.e. among those NPOs that volunteered for assuming such a task, and that fulfil the additional criteria defined in the regulations (for instance, for unitary applications, these MSs need to participate in the unitary patent system [alternative: the basic patent must have unitary effect in these MSs]; other criteria relate to the use of the Art. 10.5 exemption).

The general idea of the rotation mechanism is to appoint rapporteurs and co-rapporteurs on the basis of an alphabetical list of the names of the MSs that have volunteered to participate in SPC examination under the new regime (“the list”). The AT NPO will be the very first one to be taken into consideration when applying the rules below, since initially there will be no “last NPO”.

Under the rotation mechanism, the rapporteurs and the co-rapporteurs shall be appointed on the basis of an alphabetical list<sup>1</sup> of the names of the MSs that have volunteered to participate in SPC examination under this Regulation and Regulation xxxx (for unitary SPCs).

#### B. For purely unitary SPC applications

B1. **The rapporteur** will be the next NPO in the list, i.e. the one following the current “last NPO”, provided that its MS (1) participates in the UP system [alternative: that the basic patent has unitary effect in that MS] and (2) does not make use of the Art. 10.5 exemption. Should these two requirements not be met, the next-following NPO in the list will be considered, and so on until these two requirements are met (in other words, NPOs not meeting these requirements will be ‘skipped’). That NPO will now be considered as the new “last NPO”.

B2. The **first co-rapporteur** will then be selected by applying the same rules as in B1. That NPO will now be considered as the new “last NPO”.

B3. The **second co-rapporteur** will be the next NPO in the list, i.e. the one following the current “last NPO”, provided that its MS participates in the UP system [alternative: that the basic patent has unitary effect in that MS]. Should that requirement not be met, the next-following NPO in the list will be considered, and so on until that requirement is met (in other words, NPOs which do not participate in the UP system will be ‘skipped’). That NPO will now be considered as the new “last NPO”.

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<sup>1</sup> To be clarified which list will be used. Options include: two letter EUROSTAT or ISO country codes. Delegations are encouraged to share their preference. For the first application, the list will start with the AT NPO, which will be the first one to be taken into consideration, since, according to the system proposed, initially there will be no “last NPO”.

### C. For combined SPC applications

C1. *[same as B1]* **The rapporteur** will be the next NPO in the list, i.e. the one following the current “last NPO”, provided that its MS (1) participates in the UP system [alternative: that the basic patent has unitary effect in that MS] and (2) does not make use of the Art. 10.5 exemption. Should these two requirements not be met, the next-following NPO in the list will be considered, and so on until these two requirements are met (in other words, NPOs not meeting these requirements will be ‘skipped’). That NPO will now be considered as the new “last NPO”.

C2. *[same as B3]* The **first co-rapporteur** will be the next NPO in the list, i.e. the one following the current “last NPO”, provided that its MS participates in the UP system [alternative: that the basic patent has unitary effect in that MS]. Should that requirement not be met, the following NPO in the list will be considered, and so on until that requirement is met (in other words, NPOs which do not participate in the UP system will be ‘skipped’). That NPO will now be considered as the new “last NPO”.

C3. The **second co-rapporteur** will be the next NPO in the list, i.e. the one following the current “last NPO”, provided that two requirements are met: (1) the MS concerned is designated with a view to the grant of a national SPC (i.e. does not participate in the UP system) [alternative: “i.e. the basic patent does not have unitary effect in that MS”]; (2) at least one of the two co-rapporteurs’ MSs does not make use of the Art. 10.5 exemption. Should these requirements not be met, the next-following NPO in the list will be considered, and so on until these two requirements are met. That NPO will now be considered as the new “last NPO”.

### D. For centralised SPC applications

D1. **The rapporteur** will be the next NPO in the list, i.e. the one following the current “last NPO”, provided that its MS does not make use of the Art. 10.5 exemption. Should that requirement not be met, the next-following NPO in the list will be considered, and so on until that requirement is met (in other words, NPOs making use of the Art. 10.5 exemption will be ‘skipped’). That NPO will now be considered as the new “last NPO”.

D2. The **first co-rapporteur** will be the next NPO in the list, i.e. the one following the current “last NPO”. That NPO will now be considered as the new “last NPO”.

D3. *[same as D1]* The **second co-rapporteur** will be the next NPO in the list, i.e. the one following the current “last NPO”, provided that it does not make use of the Art. 10.5 exemption. Should that requirement not be met, the next-following NPO in the list will be considered, and so on until that requirement is met (in other words, NPOs making use of the Art. 10.5 exemption will be ‘skipped’). That NPO will now be considered as the new “last NPO”.

### Example

Let's designate the 27 EU MSs by the letters A, B, C, ..., X, Y, Z, Z1, and let's assume that they have the following statuses as regards participation in the UP system and use of the Art. 10.5 exemption. This table (i.e. "the list") only mentions those MSs that have volunteered to participate in the examination of SPC applications under the new regime.

MSs	Participates in the UP system (18)?	Makes use of the Art. 10.5 exemption?
A	Y	N
C	Y	Y
D	Y	N
E	Y	Y
F	Y	Y
H	Y	N
I	Y	N
R	Y	N
S	N	N
T	N	Y
V	N	Y
X	N	N
Y	N	Y
Z	N	N

The table below assumes that the following SPC applications are sequentially filed (see first column), and then shows which (co-)rapporteurs are assigned to them (with the reasoning):

Application	Rapporteur	Co-rapp. 1	Co-rapp. 2	Comments
A1: unitary	A	C	D	B was skipped as co-rapp. 1 since it has not volunteered (i.e. it is not a network member); D is now the "last NPO"
A2: unitary	H	I	R	E and F were skipped as rapporteur since they make use of Art. 10.5; R is now the "last NPO"
A3: combined	S	T	X	V was skipped as the 2 <sup>nd</sup> co-rapporteur since it makes use of the Art. 10.5 exemption; X is now the "last NPO"
A4: centralised	Z	A	D	Y is skipped as it makes use of the Art. 10.5 exemption, and C as well; D is now the "last NPO"
A5: centralised	H	I	R	R is now the "last NPO"
A6: combined	A	C	D	S to Z were skipped as they do not participate in the UP system; D is now the "last NPO"